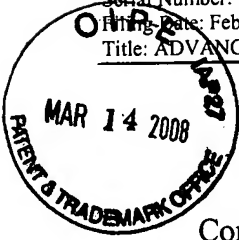


Serial Number: 10/787,045

Filing Date: February 25, 2004

Title: ADVANCED PATIENT AND MEDICATION THERAPY MANAGEMENT SYSTEM AND METHOD



IN THE DRAWINGS

Corrected drawings are supplied herewith.

Enclosed is a complete set of Replacement Sheet drawings including amended Fig. 4. Applicant has amended Fig. 4 to replace the reference number "262" for the LED display with the reference number --280-- in order to address a drawing objection on page 3 of the Office Action. No new matter has been added.

REMARKS

This responds to the Office Action dated on October 9, 2007. Claims 1, 2, 4, 8, 9, 11, 16-18, 21, and 24-28 are amended. Claim 15 is canceled. No claims are added. As a result, claims 1-14 and 16-28 are now pending in this patent application.

Applicant respectfully submits that the amendments and additions to the claims are fully supported by the specification and no new matter has been added. Applicant hereby respectfully requests further examination and reconsideration of the application in view of the following remarks.

Objections to the Drawings

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(4) because of reference character designations.

Regarding the objections listed in the paragraph numbered 2 on pages 2-3 of the Office Action, Applicant respectfully submits that the drawings are in compliance with 37 CFR 1.84(p)(4). The individual Office Action statements are addressed, as follows:

- The Office Action contends that “reference characters ‘102’, ‘104’, ‘105’, and ‘106’ have all been used to designate ‘device’ (figure 1)”. Applicant submits that reference characters 102, 104, 105, and 106 each refer to different devices. The specification on pages 6-10, describe that the devices 102, 104, 105, and 106 can be implantable or external devices. In one example, the specification at pages 9-10 describes device 105 as a medication therapy management device and device 106 as an implanted device. As such, Applicant respectfully submits that use of different reference characters to designate different devices is proper and that no correction to Fig. 1 is required to overcome this objection.
- The Office Action contends that “reference characters ‘236’ (figure 2) and ‘248’ (figure 4) have both been used to designate ‘operating system’; . . . reference characters ‘240’ (figure 2) and ‘254’ (figure 4) have both been used to designate ‘program module’; reference characters ‘242’ (figure 2) and ‘258’ (figure 4) have both been used to designate ‘program data’; reference characters ‘244’ (figure 2) and ‘246’ (figure 4) have both been used to designate ‘input device’; reference characters

‘212’ (figure 2) and ‘250’ (figure 4) have both been used to designate ‘CPU’”.

Applicant submits that Fig. 2 portrays a computer system 200 (*see* Specification at page 4, lines 28-29, and page 9, lines 17-27) and Fig. 4 portrays a medication therapy management device communications and control system 211 (*see* Specification at page 5, lines 3-4, and page 11, lines 10-21). As such, Applicant respectfully submits that each of the pairs of elements listed above, while having similar names, are actually different elements, with one element of each of the pairs being a part of an example of a computer system 200 (Fig. 2) and the other element of each of the pairs being a part of an example of a medication therapy management device communications and control system 211 (Fig. 4). As such, Applicant respectfully submits that use of different reference characters to designate different elements is proper and that no correction to either Fig. 2 or 4 is required to overcome this objection.

- The Office Action contends that “reference characters ‘214’ (figure 2), ‘154’ (figure 5) and ‘252’ (figure 4) have all been used to designate ‘memory’”. Applicant submits that Fig. 2 portrays a computer system 200 (*see* Specification at page 4, lines 28-29, and page 9, lines 17-27), Fig. 5 portrays an interrogator/transceiver unit 190 (*see* Specification at page 5, lines 5-6, and page 16, line 14 – page 17, line 2), and Fig. 4 portrays a medication therapy management device communications and control system 211 (*see* Specification at page 5, lines 3-4, and page 11, lines 10-21). As such, Applicant respectfully submits that each of the elements listed above, while having similar names, are actually different elements, with memory 214 being a part of an example of a computer system 200 (Fig. 2), memory 154 being a part of an example of an interrogator/transceiver unit 190 (Fig. 5), and memory 252 being a part of an example of a medication therapy management device communications and control system 211 (Fig. 4). As such, Applicant respectfully submits that use of different reference characters to designate different memory elements is proper and that no correction to any of Figs. 2, 4, or 5 is required to overcome this objection.
- The Office Action contends that “reference characters ‘304’, ‘306’, ‘308’, and ‘310’ have all been used to designate ‘computer system’ (figure 6); reference characters

‘316’ (figure 6) and ‘320’ (figure 6) have both been used to designate ‘database’; and reference characters ‘318’ (figure 6) and ‘322’ (figure 6) have both been used to designate ‘server computers’.” Applicant submits that reference characters 304, 306, 308, and 310 each refer to different computer systems in a plurality of computer systems; reference characters 316 and 320 each refer to different databases; and reference characters 318 and 322 each refer to different server computers (*see* Specification at page 20, line 26 – page 21, line 11). As such, Applicant respectfully submits that use of different reference characters to designate different devices is proper and that no correction to Fig. 6 is required to overcome this objection.

For at least these reasons, respectfully submits that the drawings are in compliance with 37 CFR 1.84(p)(4). Accordingly, Applicant respectfully requests reconsideration and withdrawal of these objections to the drawings.

Regarding the objections listed in the paragraph numbered 3 on page 3 of the Office Action, Applicant has amended the drawings to address “reference character ‘262’ [being] used to designate both ‘LED display’ (figure 4) and ‘housing’ (figure 3)”. Specifically, Applicant has amended Fig. 4 to replace the reference number “262” for the LED display with the reference number --280--. In view of this drawing amendment, Applicant respectfully requests reconsideration and withdrawal of this drawing objection.

Regarding the objection in which the Office Action contends that “reference character ‘105’ has been used to designate both ‘device’ (figure 1) and ‘medicine therapy management device’ (figure 6)”, Applicant submits that, in one example, “device 105 is a medication therapy management device”. (*See* Specification at page 9, lines 28-29.) As such, Applicant respectfully submits that reference number 105 designating “device” in Fig. 1 and “medicine therapy management device” in Fig. 6 is proper and that no correction to Fig. 1 or 6 is required to overcome this objection. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this objection to the drawings.

§102 Rejection of the Claims

Claims 9-28 were rejected under 35 U.S.C. § 102(b) for anticipation by Yarin et al. (U.S. Patent No. 6,294,999). In view of the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

Initially, Applicant canceled claim 15, thereby rendering the rejection of claim 15 moot.

Applicant cannot find in Yarin et al. each and every recitation of claims 9-14 and 16-28. For instance, with respect to amended claim 9 and claims 10-14 and 16-23 dependent therefrom, Applicant cannot find in Yarin et al.:

a medical measurement device for measuring data related to at least one patient physiological health factor including fluid retention data;

a medication therapy management device, configured to house diuretic medication and store data related to patient consumption of medication, the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement device and the data related to patient consumption of medication; and

a patient wellness host system, communicatively coupled to the medication therapy management device, configured to receive and display the processed data and use the processed data to generate a diuretic medication therapy regimen.

Applicant cannot find any description in Yarin et al. directed to a medical measurement device that measures fluid retention data, nor can Applicant find in Yarin et al. a patient wellness host system that uses processed data to generate a diuretic medication therapy regimen.

Although the Office Action at page 5 contends that Yarin et al. shows “at least one patient physiological health factor compris[ing] fluid retention data”, Applicant cannot find in any of the cited portions (or any other portions of Yarin et al.) the Yarin et al. device using fluid retention data. Instead, it appears that Yarin et al. describes “communication with various appliances” like “personal computers 22a, Web TVs 22b, weight scales 22c, refrigerators 22d, exercise devices 22e, and scanners 22f.” (Yarin et al. at col. 5, lines 51-54.) Yarin et al. goes on to describe “a receptacle [of the Smart Tray] that is configured to removably receive and interact with various objects” like “blood pressure monitors, thermometers, pagers, glucometers, prothrombin and coagulation monitors.” (Yarin et al. at col. 6, lines 39-44.) As such, Applicant cannot find in

Yarin et al. any description related to a medical measurement device that measures fluid retention data, much less a medication therapy management device configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement device and the data related to patient consumption of medication or a patient wellness host system configured to use the processed data to generate a diuretic medication therapy regimen, as is recited or incorporated in claims 9-14 and 16-23.

Regarding claim 24 and claims 25-28 dependent therefrom, Applicant cannot find in Yarin et al.:

- alerting a patient when it is time to carry out a diuretic medication step of a first therapeutic plan;
- sensing when the medication containment unit is engaged and recording the same as a medication event;
- implantably sensing fluid retention data;
- receiving patient physiological data including the implantably-sensed fluid retention data;
- processing said patient physiological data and said medication event data; and
- generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data.

For reasons similar to those stated above with respect to claims 9-14 and 16-23, Applicant cannot find in Yarin et al. sensing fluid retention data or processing such data and using such processed data to generate a second therapeutic plan. Moreover, Applicant can find no mention in Yarin et al. of implantably sensing fluid retention data. As is apparent from the above-cited portions of Yarin et al., Yarin et al. does not seem to contemplate implantable devices to sense data. As such, Applicant cannot find in Yarin et al. each and every recitation of claim 24 or claims 25-28 dependent therefrom.

Therefore, because Applicant cannot find all elements presently recited or incorporated in claims 9-14 and 16-28 in Yarin et al., Applicant respectfully requests withdrawal of this rejection. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

§103 Rejection of the Claims

Claims 1-8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Warkentin et al. (U.S. Patent No. 6,471,645) in view of Yarin et al. In view of the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

Applicant respectfully submits that obviousness does not presently exist because the references, in combination with the reasoning of the Office Action, do not appear to fully encompass the subject matter of claims 1-8. For instance, with respect to amended claim 1, Applicant cannot find in the references, in combination with the reasoning set forth in the Office Action:

- an implantable device configured to monitor fluid retention;
- a containment unit configured to accessibly house diuretic medication; and
- a health management host system coupled to the containment unit in a manner that allows data transmission, said containment unit including a communications and control system that records and transmits data relating to a medication event, said containment unit control system further providing for transmitting and receiving medication therapy data; said health management host system configured to receive data related to the medication event, receive patient physiological data including fluid retention data collected by the implantable device, analyze and display the patient physiological data and the medication event data on a health management display, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data.

Applicant cannot find in the references, in combination with the reasoning set forth in the Office Action, an implantable device configured to monitor fluid retention or a health management host system configured to generate a diuretic medication therapy regimen using the analysis of the patient physiological data (including the fluid retention data) and the medication event data. For reasons similar to those stated above, Applicant can find no mention in Yarin et al. of implantable devices that monitor fluid retention or of using such data to generate a diuretic medication therapy regimen. Additionally, Applicant cannot find in Warkentin et al. any description regarding implantable devices that monitor fluid retention or of using such data to generate a diuretic medication therapy regimen. Warkentin et al. states that “TMD 10 contains a

microprocessor for timing, sensing and pacing functions consistent with preset programmed functions. Similarly, IMDs 10' and 10" are microprocessor-based to provide timing and sensing functions to execute the clinical functions for which they are employed. For example, IMD 10' could provide neural stimulation to the brain via electrode 30 and IMD 10" may function as a drug delivery system that is controlled by electrode 36." (Warkentin et al. at col. 6, lines 30-37.) As such, Applicant cannot find in the references, in combination with the reasoning set forth in the Office Action, an implantable device configured to monitor fluid retention or a health management host system configured to generate a diuretic medication therapy regimen using the analysis of the patient physiological data (including the fluid retention data) and the medication event data. For at least this reason, Applicant respectfully submits that the references, in combination with the reasoning set forth in the Office Action, does not show each and every recitation of claim 1.

Dependent claims 2-8 depend from independent claim 1. Accordingly, these claims incorporate the features of claim 1. For reasons analogous to those stated above with respect to claim 1, claims 2-8 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 1-8 are allowable over the references, in combination with the reasoning set forth in the Office Action, and respectfully requests reconsideration and withdrawal of this rejection.

RESERVATION OF RIGHTS

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any canceled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date

March 10, 2008

By

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CERTIFICATE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10 day of March 2008.

Name

Nicole J. Allen

Signature

[Signature]